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AS ↓ V	AA1	4,683,195	07/28/1987	Mullis <i>et al.</i>			02/07/1986
	AB1	5,264,618	11/23/1993	Felgner <i>et al.</i>			04/16/1991
	AC1	5,389,540	02/14/1995	Makoff <i>et al.</i>			11/27/1990
	AD1	5,443,966	08/22/1995	Fairweather <i>et al.</i>			08/23/1993
	AE1	5,459,127	10/17/1995	Felgner <i>et al.</i>			09/16/1993
	AF1	5,571,694	11/05/1996	Makoff <i>et al.</i>			07/25/1994
	AG1	5,580,859	12/03/1996	Felgner <i>et al.</i>			03/18/1994
	AH1	5,591,631	01/07/1997	Leppla <i>et al.</i>			02/12/1993
	AI1	5,643,578	07/01/1997	Robinson <i>et al.</i>			01/27/1993
	AJ1	5,677,274	10/14/1997	Leppla <i>et al.</i>			06/25/1993
AS	AK1	5,747,028	05/05/1998	Calderwood <i>et al.</i>			06/07/1995
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EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
AS	AL1	CA 2,001,508	04/25/1990	Canada			X Yes No
AS	AM1	EP 0 366 550 A1	05/02/1990	Europe			X Yes No
AS	AN1	WO 90/04637 A1	05/03/1990	WIPO			X Yes No
AS	AO1	WO 94/18332 A2	08/18/1994	WIPO			Yes No
AS	AP1	WO 94/19482 A1	09/01/1994	WIPO			Yes No
<b>OTHER (Including Author, Title, Date, Pertinent Pages, etc.)</b>							
AS	AR	1	Agrawal, A., <i>et al.</i> , "Impairment of dendritic cells and adaptive immunity by anthrax lethal toxin," <i>Nature</i> 424:329-334, Nature Publishing Group (July 2003)				
AS	AS	1	Aihara, H. and Miyazaki, J-I., "Gene transfer into muscle by electroporation in vivo," <i>Nat. Biotechnol.</i> 16:867-870, Nature America Publishing (1998)				
AS	AT	1	Anderson, R., <i>et al.</i> , "Immunization of mice with DNA encoding fragment C of tetanus toxin," <i>Vaccine</i> 15:827-829, Elsevier (1997)				
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AS	AA2	5,837,693	11/17/1998	German <i>et al.</i>			03/24/1995
	AB2	5,840,312	11/24/1998	Mock <i>et al.</i>			10/19/1994
	AC2	5,861,397	01/19/1999	Wheeler			10/03/1996
	AD2	5,994,317	11/30/1999	Wheeler			04/09/1996
	AE2	6,004,944	12/21/1999	Rothman <i>et al.</i>			10/02/1997
	AF2	6,022,874	02/08/2000	Wheeler			12/23/1998
	AG2	6,224,870	05/01/2001	Segal			01/15/1998
	AH2	6,267,966 B1	07/31/2001	Baillie			08/26/1997
	AI2	6,316,006 B1	11/13/2001	Worsham <i>et al.</i>			11/23/1994
	AJ2	6,387,665 B1	05/14/2002	Ivins <i>et al.</i>			03/07/2000
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AS	AL2	WO 98/08952 A1	05/05/1998	WIPO			Yes No
AS	AM2	WO 98/11914 A1	03/26/1998	WIPO			Yes No
AS *	AN2	CA 2,202,322	06/20/1998	Canada			Yes No
AS	AO2	WO 00/02522 A2	01/20/2000	WIPO			Yes No
AS	AP2	WO 00/02591 A1	01/20/2000	WIPO			Yes No

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AS	AR	2	André, S., <i>et al.</i> , "Increased Immune Response Elicited by DNA Vaccination with a Synthetic gp120 Sequence with Optimized Codon Usage," <i>J. Virol.</i> 72:1497-1503, American Society for Microbiology (1998)
AS	AS	2	Darquet, A.-M., <i>et al.</i> , "A new vehicle for nonviral gene delivery: supercoiled minicircle," <i>Gene Ther.</i> 4:1341-1349, Stockton Press (1997)
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	AC3	6,670,332 B1	12/30/2003	Wheeler			06/05/1998
	AD3	6,696,424 B1	02/24/2004	Wheeler			05/26/2000
	AE3	5,589,466	12/31/1996	Felgner <i>et al.</i>			01/26/1995
	AF3	6,214,804 B1	04/10/2001	Felgner <i>et al.</i>			06/07/1995
	AG3	5,703,055	12/30/1997	Felgner <i>et al.</i>			01/26/1994
	AH3	6,710,035 B2	03/23/2004	Felgner <i>et al.</i>			12/02/1999
	AI3	2001/0031264 A1	10/18/2001	Segal			02/21/2001
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AS	AL3	WO 00/56282 A1	09/28/2000	WIPO			Yes No
AS	AM3	WO 00/57917 A2	10/05/2000	WIPO			Yes No
AS	AN3	WO 01/19395 A1	03/22/2001	WIPO			Yes X No
AS	AO3	WO 01/34801 A2	05/17/2001	WIPO			Yes No
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AS	AR	3	Deml, L., <i>et al.</i> , "Multiple Effects of Codon Usage Optimization on Expression and Immunogenicity of DNA Candidate Vaccines Encoding the Human Immunodeficiency Virus Type 1 Gag Protein," <i>J. Virol.</i> 75:10991-11001, American Society for Microbiology (November 2001)
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AS	AT	3	Duesbery, N.S., <i>et al.</i> , "Proteolytic Inactivation of MAP-Kinase-Kinase by Anthrax Lethal Factor," <i>Science</i> 280:734-737, American Association for the Advancement of Science (1998)

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AS	AL4	WO 02/00844 A2	01/03/2002	WIPO			Yes No
	AM4	GB 2,370,772 A	07/10/2002	Great Britain			Yes No
	AN4	WO 04/024067 A2	03/25/2004	WIPO			Yes No
	AO						Yes No
AS	AP						Yes No

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AS	AR	4	Felgner, P.L., <i>et al.</i> , "Lipofection: A highly efficient, lipid-mediated DNA-transfection procedure," <i>Proc. Natl. Acad. Sci. USA</i> 84:7413-7417, National Academy of Sciences (1987)
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AS	AA5	2004/0157244 A1	08/12/2004	Budahazi <i>et al.</i>			11/24/2003
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	AL						Yes No
	AM						Yes No
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AS	AR	<u>5</u>	Gramzinski, R.A., <i>et al.</i> , "Immune Response to a Hepatitis B DNA Vaccine in Aotus Monkeys: A Comparison of Vaccine Formulation, Route, and Method of Administration," <i>Molec. Med.</i> 4:109-118, The Picower Institute Press (1998)				
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AS	AT	<u>5</u>	Hammond, S.E. and Hanna, P.C., "Lethal Factor Active-Site Mutations Affect Catalytic Activity In Vitro," <i>Infection &amp; Immunity</i> 66:2374-2378, American Society for Microbiology (1998)				

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AS	AR	6	Hartikka, J., <i>et al.</i> , "An Improved Plasmid DNA Expression Vector for Direct Injection into Skeletal Muscle," <i>Human Gene Ther.</i> 7:1205-1217, Mary Ann Liebert, Inc. (1996)
AS	AS	6	Hartikka, J., <i>et al.</i> , "Electroporation-Facilitated Delivery of Plasmid DNA in Skeletal Muscle: Plasmid Dependence of Muscle Damage and Effect of Poloxamer 188," <i>Molec. Ther.</i> 4:407-415, The American Society of Gene Therapy (November 2001)
AS	AT	6	Henderson, D.W., "An Apparatus for the Study of Airborne Infection," <i>J. Hygiene</i> 50:53-68, Cambridge at the University Press (1952)

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AS	AR	<u>1</u>	Holste, D., et al., "Optimization of Coding Potentials Using Positional Dependence of Nucleotide Frequencies," <i>J. Theor. Biol.</i> 206:525-537, Academic Press (2000)
AS	AS	<u>1</u>	Horn, N.A., et al., "Cancer Gene Therapy Using Plasmid DNA: Purification of DNA for Human Clinical Trials," <i>Human Gene Ther.</i> 6:565-573, Mary Ann Leibert, Inc., Publishers (1995)
AS	AT	<u>1</u>	Ivins, B.E. and Welkos, S.L., "Recent Advances in the Development of an Improved Human Anthrax Vaccine," <i>Eur. J. Epidemiol.</i> 4:12-19, Kluwer Academic Publishers (1988)

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AS	AS	8	Klimpel, K.R., <i>et al.</i> , "Anthrax toxin protective antigen is activated by a cell surface protease with the sequence specificity and catalytic properties of furin," <i>Proc. Natl. Acad. Sci. USA</i> 89:10277-10281, National Academy of Sciences (1992)
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AS	AR	9	Kushner, N., <i>et al.</i> , "A fragment of anthrax lethal factor delivers proteins to the cytosol without requiring protective antigen," <i>Proc. Natl. Acad. Sci. USA</i> 100:6652-6657, National Academy of Sciences (May 2003)
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AS	AR	<u>10</u>	Lindmayer, I., <i>et al.</i> , "Development of New Jet Injector for Insulin Therapy," <i>Diabetes Care</i> 9:294-297, American Diabetes Association (1986)
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AS	AT	<u>10</u>	Manickan, E., <i>et al.</i> , "DNA Vaccines - A Modern Gimmick or a Boon to Vaccinology?," <i>Crit. Rev. Immunol.</i> 17:139-154, Begell House, Inc. (1997)

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	AM						Yes No
	AN						Yes No
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FORM PTO-1449

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1530.0460002/EJH/JAH  
FIRST NAMED INVENTOR  
Hermanson, G.G.  
FILING DATE  
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APPLICATION NO.  
10/658,688  
ART UNIT  
1632

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AS	AR	<u>12</u>	Mikesell, P., <i>et al.</i> , "Evidence for Plasmid-Mediated Toxin Production in <i>Bacillus anthracis</i> ," <i>Infection &amp; Immunity</i> 39:371-376, American Society for Microbiology (1983)
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AS	AR	17	Pitt, M.L.M., <i>et al.</i> , "In vitro correlate of immunity in a rabbit model of inhalational anthrax," <i>Vaccine</i> 19:4768-4773, Elsevier Science Ltd. (September 2001)
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AS	AR	<u>19</u>	Rizzuto, G., <i>et al.</i> , "Gene Electroporation Results in a High-Level Transduction of Rat Skeletal Muscle and Corrects Anemia of Renal Failure," <i>Hum. Gene Ther.</i> 11:1891-1900, Mary Ann Liebert, Inc. (2000)
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AS	AR	<u>20</u>	Shiver, J.W., <i>et al.</i> , "Replication-incompetent adenoviral vaccine vector elicits effective anti-immunodeficiency-virus immunity," <i>Nature</i> 415:331-335, Nature Publishing Company (January 2002)
AS	AS	<u>20</u>	Singh, Y., <i>et al.</i> , "The Chymotrypsin-sensitive Site, FFD <sup>315</sup> , in Anthrax Toxin Protective Antigen Is Required for Translocation of Lethal Factor," <i>J. Biol. Chem.</i> 269:29039-29046, American Society for Biochemistry and Molecular Biology, Inc. (1994)
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AS	AR	<u>21</u>	Toncheva, V., <i>et al.</i> , "Novel vectors for gene delivery formed by self-assembly of DNA with poly(L-lysine) grafted with hydrophilic polymers," <i>Biochim. et Biophys. Acta</i> 1380:354-368, Elsevier Science B.V. (1998)
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EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AS	AR	25	Zelphati, O., <i>et al.</i> , "Stable and monodisperse lipoplex formulations for gene delivery," <i>Gene Ther.</i> 5:1272-1282, Stockton Press (1998)
AS	AS	25	Entelechon GmbH, "Backtranslation tool V2.0," available at <a href="http://www.entelechon.com/eng/backtranslation.html">http://www.entelechon.com/eng/backtranslation.html</a> (downloaded July 2004)
AS	AT	25	NCBI Entrez, GenBank Report, Accession No. M30210, Lowe, J., (Entry date 1993)

EXAMINER	/Anoop Singh/	DATE CONSIDERED	04/28/2006
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EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to Applicant.

FORM PTO-1449

## INFORMATION DISCLOSURE STATEMENT

ATTY. DOCKET NO.  
1530.0460002/EJH/JAH  
FIRST NAMED INVENTOR  
Hermanson, G.G.  
FILING DATE  
September 10, 2003

APPLICATION NO.  
10/658,688  
ART UNIT  
1632

## U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA						
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	AN						Yes No
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	AP						Yes No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AS	AR	<u>26</u>	NCBI Entrez, GenBank Report, Accession No. AAA22637, Welkos, S.L., <i>et al.</i> , (Entry date 1999)
AS	AS	<u>26</u>	NCBI Entrez, GenBank Report, Accession No. M22589, Welkos, S., (Entry date 1999)
AS	AT	<u>26</u>	NCBI Entrez, GenBank Report, Accession No. AAA22569, Lowe, J., (Entry date 1993)

EXAMINER

/Anoop Singh/

DATE CONSIDERED

04/28/2006

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	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

**OTHER (Including Author, Title, Date, Pertinent Pages, etc.)**

AS	AR	<u>27</u>	File 351, Accession No. 8246987, Derwent WPI English language abstract for CA 2,001,508 (Document AL1), EP 0 366 550 A1 (Document AM1), and WO 90/04637 (Document AN1)
AS	AS	<u>27</u>	STNEasy Database, Accession No. 2001:208128, English language abstract for WO 2001019395 A1 (Document No. AN3)
AS	AT	<u>27</u>	Copy of Co-Pending U.S. Patent Application No. 10/748,853 (unpublished), inventor Wheeler, C.J., filed December 30, 2003

EXAMINER

/Anoop Singh/

DATE CONSIDERED

04/28/2006

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FORM PTO-1449  <b>INFORMATION DISCLOSURE STATEMENT</b>	ATTY. DOCKET NO. 1530.0460002/EJH/JAH	APPLICATION NO. 10/658,688
	FIRST NAMED INVENTOR Hermanson, G.G.	
	FILING DATE September 10, 2003	ART UNIT 1632

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	AM						Yes
							No
	AN						Yes
							No
	AO						Yes
							No
	AP						Yes
							No

## OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

AS	AR	<u>28</u>	Copy of Co-Pending U.S. Patent Application No. 08/486,533 (unpublished), inventors Felgner <i>et al.</i> , filed June 07, 1995.
	AS	<u>28</u>	
	AT	<u>28</u>	

EXAMINER	/Anoop Singh/	DATE CONSIDERED	04/28/2006
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Substitute for form 1449/PTO

**FIRST SUPPLEMENTAL  
INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

*(Use as many sheets as necessary)*

**Complete if Known**

Application Number	10/658,688
Filing Date	September 10, 2003
First Named Inventor	Gary Hermanson
Art Unit	1645
Examiner Name	Baskar, P.
Attorney Docket Number	1530.0460002/EJH/J-H

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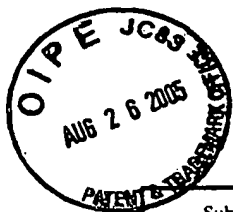
Examiner Signature	/Anoop Singh/	Date Considered	04/28/2006
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English language Translation is attached.

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<b>FIRST SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>				<b>Complete if Known</b>	
				Application Number	10/658,688
				Filing Date	September 10, 2003
				First Named Inventor	Hermanson
				Art Unit	1645
				Examiner Name	Baskar, P.
Sheet	1	of	1	Attorney Docket Number	1530.0460002/EJH/J-H

NON PATENT LITERATURE DOCUMENTS				
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author, title of the article, title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume number, publisher		T <sup>2</sup>
AS	NPL1	Okinaka, R.T., <i>et al.</i> , "Sequence and Organization of pXO1, the Large <i>Bacillus anthracis</i> Plasmid Harboring the Anthrax Toxin Genes," <i>J. Bacteriol.</i> 181:6509-6515, American Society for Microbiology (1999)		
AS	NPL2	Price, L.B., <i>et al.</i> , "Genetic Diversity in the Protective Antigen Gene of <i>Bacillus anthracis</i> ," <i>J. Bacteriol.</i> 181:2358-2362, American Society for Microbiology (1999)		
AS	NPL3	Co-pending U.S. Patent Application No. 10/843,656, inventors Vilalta, A., <i>et al.</i> , filed May 12, 2004 (NOT PUBLISHED)		
AS	NPL4	Hermanson, G., <i>et al.</i> , "A Cationic Lipid-Formulated Plasmid DNA Vaccine Confers Sustained Antibody-Mediated Protection Against Aerosolized Anthrax Spores," <i>Proc. Natl. Acad. Sci. USA</i> 101:13601-13606, National Academy of Sciences (2004)		

424012\_1.DOC

Examiner Signature	/Anoop Singh/	Date Considered	04/28/2006
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<sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> Applicant is to place a check mark here if English language Translation is attached. This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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